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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/044,692	CECH ET AL.	
	Examiner	Art Unit	
	PETER J. REDDIG	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-74,76,77 and 79-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71-74,76,77 and 79-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/21/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed March 20, 2008 in response to the Office Action of September 20, 2007 is acknowledged and has been entered. Previously pending claims 71-74, 76, 77, and 79-82 have been amended.

2. Claims 71-74, 76, 77, and 79-82 are currently being examined.

3. The following rejections are being maintained:

Claim Rejections - 35 USC § 112

4. Claims 74, 76, 77, 80, and 82 remain rejected under 35 USC 112, first paragraph essentially for the reasons previously set forth in section 5, pages 2-7 of the Office Action of September 20, 2007.

Applicants argue that the Examiner argued, that although one of skill reading the specification would immediately envision fragments of SEQ ID NO:2, "one would not immediately envision immunogenic fragments that will elicit an adaptive immune response against SEQ ID NO:2.'" Applicants argue that the Examiner argued also stated the specification provided "no guidance drawn to the fragments that will function as claimed" (i.e., which fragments will elicit an adaptive immune response). Applicants argue that the Examiner argued that it was unpredictable that antibodies elicited by "linear" hTRT peptides will bind to the full length antigens Applicants argue that the Examiner asserted that nucleic acids encoding a polypeptide "comprising" at least 10 contiguous amino acids of SEQ. ID NO:2 was "clearly undefined" because, "it is not possible to determine the structures of fragments "'comprising" or to determine the effect of additional amino acids on the immunogenicity of the claimed fragments "comprising." Applicants argue that the Examiner acknowledged that full-length hTRT (1132 amino acids in length) will elicit an adaptive immune response. Applicants argue

that it would not be disputed by the Office that a fragment consisting of 1131 amino acids would also be immunogenic.

Applicants' arguments have been considered, but have not been found persuasive. although SEQ ID NO: 2 and proteins comprising SEQ ID NO: 2 would predictably produce an adaptive immune response to itself, Applicants are arguing limitations, a fragment consisting of 1131 amino acids that would also be immunogenic, that are not found in the claims.

Applicants argue that the first concern of the Office appears to be that some small fragments might not elicit an adaptive immune response against hTRT or might not elicit an adaptive immune response that would include antibodies that recognize hTRT in the native conformation Applicants argue that that the claims do not require that antibodies elicited by the claimed compositions bind hTRT in the native conformation. Antibodies that bind denatured hTRT are also useful.

Applicants' arguments have been considered, but have not been found persuasive. Although Antibodies that bind denatured hTRT may be useful for such things as immunoblotting, one of skill in the art could not predictably visualize which of the claimed fragments of SEQ ID NO: 2 will produce an adaptive immune response against SEQ ID NO: 2, whether it is denatured or not given, the unpredictability in the art previously set forth.

Applicants argue that as evidence that a short peptide might not elicit an immune response that recognizes native human TRT, Examiner Ungar cited Holmes et al., 2001, Exp. Opin. Invest. Drugs 10(3):511-519, as teaching that "none of the antibodies [generated by synthetic peptides] exhibited binding to the full length antigen." Applicants argue that although the antibodies described in Holmes did not bind to full length protein, this does not indicate that

antibodies generated by the peptides of the claimed invention would not bind to full length protein. The synthetic peptides used in Holmes, aa63-68, aa132-137 or aa 482-487 (p. 513, col. 1) consist of only 5 amino acids rather than polypeptides that are at least 10 consecutive amino acids in length as claimed in the present invention. In fact, the Holmes et al. reference concluded that "The observation ... perhaps can be overcome by the use of slightly longer eight amino acid peptides as was utilized by Murphy et al." (p. 513, col. 1). Holmes also teaches that the antibody utilized by Murphy was capable of immunoprecipitating native full length protein (p. 512, col. 2). Applicants argue that, thus, the Holmes et al. reference does not support the Examiner's assertions.

Applicants' arguments have been considered, but have not been found persuasive. First, claim 77 (b) is not limited to an immunogenic fragment of any particular size, thus they encompass fragments smaller than 8 or 10 amino acids. Although Holmes teaches that an eight amino acid peptide produced an immune response that could recognize the full length protein, the teachings of the specification have not given guidance or direction as to which peptides of SEQ ID NO: 2 would elicit an adaptive immune response against SEQ ID NO: 2. Additionally, Tanaka et al. (1985 Proc. Natl. Acad. Sci USA 82:3400-3404) tested 35 synthetic peptides of length varying from 7 to 20 amino acid residues for generation of antibodies, and report that while 31 of 32 peptides of more than 10 residues induced antibodies only 56% of the antipeptide antibodies produced reacted with the native protein, see Abstract, page 3401-3402 and Table 1. Additionally, Tanaka et al. teach that all peptides of fewer than 10 residues did not induce antibody production and only 1 of 7 peptides of fewer than 13 amino acids produced antibodies that reacted with the native antigen, see Abstract, page 3403, 1st col., and Fig. 1. Thus without

further guidance, one of skill in the art could not readily envision which of the claimed peptides will elicit an adaptive immune response against SEQ ID NO: 2 and one would skill in the art would not recognize that Applicants were in possession of the claimed genus.

Applicants argue that provided with the disclosure of the hTRT protein sequence --a discovery of enormous scientific and medical significance-- and the teachings of the lengthy specification, one of skill in the art would have recognized the inventors' had "possession" of hTRT fragments that will elicit an adaptive immune response in humans and other animals. Moreover, methods of determining immunogenic portions of protein antigens are described in the specification and were well known in the art. This knowledge includes how to determine the ability of an hTRT fragment to generate both T-cell and B-cell immune response. For example, immunogenicity of an hTRT fragment can be determined at a practical level by injecting the fragment and an adjuvant into an animal and then assaying for the appearance of antibodies directed against the injected peptide (see the specification at, e.g., paragraphs [0204]).

Applicants' arguments have been considered, but have not been found persuasive. Although one of ordinary skill could screen for the species that would function as claimed by injecting the fragment and an adjuvant into an animal and then assaying for the appearance of antibodies directed against the injected peptide or SEQ ID NO: 2, screening assays do not enable the claimed invention because the court found in (*Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004) that screening assays are not sufficient to enable an invention because they are merely a wish or plan for obtaining the claimed chemical invention.

Applicants argue that having been provided by the inventors with the (previously unknown) sequence of hTRT, one of skill at the priority date of the invention would have been

able to use art-known methods to predict fragments that were likely to be most immunogenic. For example, a copy of pages 25- 52 of a text book entitled "Vaccine Design" (1993) by F. Brown et al. is provided in the supplemental information disclosure statement (IDS) concurrently submitted. Chapter 4 of this reference explains how epitopes can be predicted from amino acid sequence information. The common knowledge of one of ordinary skill in the art would have included the prediction of B- cell epitopes and/or T-cell epitopes in a full length protein. Specifically, one skilled in the art could have predicted the most likely linear (B-cell) epitopes using the sorts of procedures described on pages 34-38 of "Vaccine Design." T-cell epitopes could have been predicted by the procedures described on pages 39-43 of this reference.

Applicants' arguments have been considered, but have not been found persuasive. Although one of ordinary skill could screen for the species that would function as claimed, screening assays do not enable the claimed invention for the reasons set forth above. Given that Flower (Trends in Immunology, 2003, 24: 667-674) teaches, as previously set forth, the accurate prediction of epitopes to which the antibody would bind is difficult and the complexity of immunogenic epitopes continually confounds efforts at prediction, one of skill in the art could not readily envision which of the claimed peptides will elicit an adaptive immune response against SEQ ID NO: 2 and one of skill in the art would not recognize that Applicants were in possession of the claimed genus.

Applicants argue that as a practical matter, the average skilled person would have been able to use algorithms that not only identified MHC binding motifs, but were also able to rank them according to relative binding strength. For example, Parker et al.(J. Immunology 152:163-175 (1994)) discusses a scheme for ranking potential HLA-A2 binding peptides. Numerous

publications in the art disclosing algorithms for peptides with MHC II binding motifs (see, e.g., Davenport et al., 1995, Immunogenetics 42:392-397; Meister et al., 1995, Vaccine 13: 581-591; and pages 76-78 of Hammer et al., 1997, Advances in Immunology 66:67-100). Furthermore, it was standard practice to identify peptides comprising MHC binding motifs by generating overlapping peptides spanning the sequence of a protein antigen and then test these peptides for the ability to stimulate a T-cell response (see Meister, page 581, paragraph 2). This peptide search technique predicted all the known T-cell epitopes in five model proteins tested (see Table 3 of Meister). Based on at least these reasons, it would have been clear to the skilled artisan that the inventors, having cloned and characterized the human TRT gene, could select immunogenic fragments of SEQ ID NO:2

Applicants' arguments have been considered, but have not been found persuasive. Although one of ordinary skill could screen for the species that would function as claimed, screening assays do not enable the claimed invention for the reasons set forth above.

Applicants' arguments in regard to the transitional term "comprising" have been considered, and have been found persuasive.

However, in total, Applicant's arguments have not been found persuasive and the rejection is maintained.

New Grounds of Rejection/Objection

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figures 10 A and B and 22 A-D and. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance

with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 74, 76, 77, and 80 are rejected under 35 U.S.C. 102(a) as being anticipated by AA281296, NCI-CGAP http://www.ncbi.nlm.nih.gov/ncicgap (National Cancer Institute, Cancer Genome Anatomy Project (CGAP), April 2, 1997) as evidenced by Appendices 1 and 2 which show the date of first appearance of AA281296 and the pT7T3 vector, respectively.

The claims are drawn to:

74. A composition containing a nucleic acid sequence encoding a polypeptide consisting of at least 10 contiguous amino acids of SEQ. ID NO:2, wherein said nucleic acid sequence is

operably linked to a promoter, and wherein the composition elicits an adaptive immune response against hTRT (SEQ. ID NO:2) when administered to a subject.

76. A composition containing a nucleic acid sequence encoding a polypeptide that comprises at least 10 contiguous amino acids of SEQ. ID NO:2, wherein said nucleic acid sequence is operably linked to a promoter, and wherein the composition elicits an adaptive immune response against hTRT (SEQ. ID NO:2) when administered to a subject.

77. A composition containing a nucleic acid sequence encoding a polypeptide selected from: (a) the amino acid sequence SEQ ID NO:2; and, (b) an immunogenic fragment of SEQ ID NO:2, wherein said nucleic acid sequence is operably linked to a promoter, and wherein the composition, when administered to a subject, induces an adaptive immune response against hTRT (SEQ ID NO:2).

80. A composition containing a plasmid vector encoding a polypeptide that comprises at least 10 contiguous amino acids of SEQ. ID NO:2, wherein when the composition is administered to a subject, the polypeptide is expressed and elicits an adaptive immune response against hTRT (SEQ. ID NO:2).

AA281296 teaches a nucleic acid sequence encoding a polypeptide consisting of at least 10 contiguous amino acids of SEQ ID NO:2 wherein the nucleic acid sequence is operably linked to the T3 and T7 promoter of the pT7T3-Pac vector as the sequence is cloned into the Not I and EcoR I sites between the T3 and T7 promoters.

It is noted that the specification teaches that the term "operably linked" refers to a functional relationship between two or more nucleic acid (e.g., DNA) segments: for example, a promoter or enhancer is operably linked to a coding sequence if it stimulates the transcription of

the sequence in an appropriate host cell or other expression system, see para 0468 of the published Application. Thus, given this non-limiting definition of "operably linked" and given that the T7 and T3 promoters are linked to AA281296 and are well known in the art to stimulate transcription of linked sequences, AA281296 is operably linked to a promoter.

Additionally, in the absence of a limiting definition of an immunogenic fragment of SEQ ID NO: 2 in claim 77(b), given its broadest reasonable interpretation, an immunogenic fragment of SEQ ID NO: 2 reads on any size fragment of SEQ ID NO: 2.

The product of the prior art comprises the same product as claimed in the instant invention, a nucleic acid sequence encoding a polypeptide consisting of at least 10 contiguous amino acids of SEQ. ID NO:2 or an immunogenic fragment of SEQ ID NO: 2, wherein said nucleic acid sequence is operably linked to a promoter and wherein the nucleic acid is in a vector, thus the claimed product is anticipated because the product will inherently be an antibody against the human C-terminal peptide of GPC3. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Although the reference does not specifically state that the nucleic acids encoding the fragments of SEQ ID NO: 2 elicits an adaptive immune response against hTRT (SEQ. ID NO:2) when administered to a subject, the claimed product appears to be the same as the prior art product, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 71-74, 76-77 and 79-82 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 4, and 7-10 of U.S. Patent No. 6, 261,836 essentially for the reasons previously set forth in the paper mailed September 20, 2007, Section 7, pages 8-9 and in view of US Patent No. 4,889,806 and Sambrook et al (Molecular Cloning, A Laboratory Manual, Cold Spring Harbor, 1989, p. 16.3-36.)

The claims of U.S. Patent No. 6, 261,836 are drawn to polynucleotides encoding SEQ ID NO: 224, which is identical to SEQ ID NO: 2 of the instant application, but do not claim a plasmid vector or operably linking the sequences to a promoter.

US Patent No. 4,889,806 teach that with the advent of recombinant DNA and molecular cloning technology it is now conventional to transfer genetic information into plasmids or

vectors constructed in vitro and then transferred into host cells and clonally propagated (col 1, lines 18-24).

Sambrook et al teach that cloned genes are conventionally expressed using expression vectors that have promoters and that expression of cloned proteins have been used to: (1) confirm the identity of a cloned gene by using immunological or functional assays to detect the encoded protein; (2) produce large amounts of proteins of biological interest that are normally available in only limited quantities from natural sources; (3) to study the biosynthesis and intracellular transport of proteins following their expression in various cell types; and (4) to elucidate structure-function relationships by analyzing the properties of normal and mutant proteins (see pages 16.3 and 16.4 in particular).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to put the sequences of U.S. Patent No. 6, 261,836 in plasmid vectors operably linked to promoters as taught by Sambrook et al and US Patent No. 4,889,806 because US Patent No. 4,889,806 specifically teaches that it is conventional to transfer genetic materials into plasmids or vectors and then transfer the plasmids or vectors into host cells and clonally propagate the genetic material and because Sambrook et al teach that cloned genes are conventionally expressed using expression vectors. One of ordinary skill in the art at the time the invention was made would have been motivated to put the sequences of U.S. Patent No. 6, 261,836 in plasmid vectors operably linked to promoters as Sambrook et al and US Patent No. 4,889,806 because Sambrook et al specifically teach that expressed cloned proteins are used to: (1) confirm the identity of a cloned gene by using immunological or functional assays to detect the encoded protein; (2) produce large amounts of proteins of biological interest that are

normally available in only limited quantities from natural sources; (3) to study the biosynthesis and intracellular transport of proteins following their expression in various cell types; and (4) to elucidate structure-function relationships by analyzing the properties of normal and mutant proteins.

Applicants argue that they will provide a terminal disclaimer or otherwise respond to this rejection upon indication that the claims are otherwise allowable.

Given that no terminal disclaimer or arguments have been presented, the rejection is maintained.

8. Claims 71-74, 76-77 and 79-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 5-9 of U.S. Patent No. 7,262,288 in view of US Patent No. 4,889,806 and Sambrook et al (Molecular Cloning, A Laboratory Manual, Cold Spring Harbor, 1989, p. 16.3-36.)

The claims of U.S. Patent No. 7,262,288 are drawn to polynucleotides encoding telomerase reverse transcriptase proteins comprising sequences of varying identity to SEQ ID NO: 2, which is identical to SEQ ID NO: 2 of the instant application, but do not claim a plasmid vector. Although the claims of U.S. Patent No. 7,262,288 are not specifically drawn to nucleotides encoding only SEQ ID NO: 2, nucleotides encoding SEQ ID NO: 2 are clearly a contemplated embodiment of the claimed genus, see Figures 16 and 17 and col. 4.

US Patent No. 4,889,806 teach that with the advent of recombinant DNA and molecular cloning technology it is now conventional to transfer genetic information into plasmids or vectors constructed in vitro and then transferred into host cells and clonally propagated (col 1, lines 18-24).

Sambrook et al teach that cloned genes are conventionally expressed using expression vectors that have promoters and that expression of cloned proteins have been used to: (1) confirm the identity of a cloned gene by using immunological or functional assays to detect the encoded protein; (2) produce large amounts of proteins of biological interest that are normally available in only limited quantities from natural sources; (3) to study the biosynthesis and intracellular transport of proteins following their expression in various cell types; and (4) to elucidate structure-function relationships by analyzing the properties of normal and mutant proteins (see pages 16.3 and 16.4 in particular).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to put the sequences of U.S. Patent No. 7,262,288 in plasmid vectors operably linked to promoters as taught by Sambrook et al and US Patent No. 4,889,806 because US Patent No. 4,889,806 specifically teaches that it is conventional to transfer genetic materials into plasmids or vectors and then transfer the plasmids or vectors into host cells and clonally propagate the genetic material and because Sambrook et al teach that cloned genes are conventionally expressed using expression vectors. One of ordinary skill in the art at the time the invention was made would have been motivated to put the sequences of U.S. Patent No. 7,262,288 in plasmid vectors operably linked to promoters as Sambrook et al and US Patent No. 4,889,806 because Sambrook et al specifically teach that expressed cloned proteins are used to: (1) confirm the identity of a cloned gene by using immunological or functional assays to detect the encoded protein; (2) produce large amounts of proteins of biological interest that are normally available in only limited quantities from natural sources; (3) to study the biosynthesis and intracellular transport of proteins following their expression in various cell types; and (4) to

elucidate structure-function relationships by analyzing the properties of normal and mutant proteins.

9. Claims 71-74, 76-77 and 79-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,927,285.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-9 of U.S. Patent No. 6,927,285 which have all of the characteristics of the instantly claimed invention. In particular, the claims of U.S. Patent No. 6,927,285 are drawn to plasmids encoding human reverse transcriptase (pGRN121 comprises the polynucleotide encoding hTRT see Example 17 which has a T7 promoter, see Figure 49) and polynucleotides encoding protein comprising sequences of varying identity to SEQ ID NO: 173, which is identical to SEQ ID NO: 2 of the instant application.

Additionally, given the identity of the sequences of U.S. Patent No. 6,927,285 to those of the instant Application and given Applicants repeated statements that such nucleic acids will induce an adaptive immune response to SEQ ID NO: 2, the nucleic acids would inherently induce an immune response when administered to a subject. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA).

10. Claims 71-74, 76-77 and 79-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 15-19 of U.S. Patent No. 6,921,664.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-10 and 15-19 of U.S. Patent No. 6,921,664 which have all of the characteristics of the instantly claimed invention. In particular, the claims of U.S. Patent No. 6,921,664 are drawn to a recombinant expression vectors that comprise SEQ ID NO: 224 polynucleotides or variants thereof and polynucleotides encoding SEQ ID NO: 225, SEQ ID NO: 224 encodes SEQ ID NO: 225 which is identical to SEQ ID NO: 2 of the instant application, see Fig. 53 of U.S. Patent No. 6,921,664.

Given the identity of the sequences of U.S. Patent No. 6,921,664 to those of the instant Application and given Applicants repeated statements that such nucleic acids will induce an adaptive immune response to SEQ ID NO: 2, the nucleic acids of U.S. Patent No. 6,921,664 would inherently induce an immune response when administered to a subject. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA).

11. Claims 71-74, 76-77 and 79-82 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending

Application No. 11/894,562 in view of US Patent No. 4,889,806 and Sambrook et al (Molecular Cloning, A Laboratory Manual, Cold Spring Harbor, 1989, p. 16.3-36.)

Sambrook et al (Molecular Cloning, A Laboratory Manual, Cold Spring Harbor, 1989, p. 16.3-36.)

The claims of copending Application No. 11/894,562, which is a continuation of the instant application are drawn to compositions containing a nucleic acid encoding a polypeptide consisting of SEQ. ID NO:2, wherein the composition elicits an adaptive immune response against hTRT (SEQ. ID NO:2) when administered to a subject, plasmid vector encoding said sequences, and fragments and variants thereof.

US Patent No. 4,889,806 teach that with the advent of recombinant DNA and molecular cloning technology it is now conventional to transfer genetic information into plasmids or vectors constructed in vitro and then transferred into host cells and clonally propagated (col 1, lines 18-24).

Sambrook et al teach that cloned genes are conventionally expressed using expression vectors that have promoters and that expression of cloned proteins have been used to: (1) confirm the identity of a cloned gene by using immunological or functional assays to detect the encoded protein; (2) produce large amounts of proteins of biological interest that are normally available in only limited quantities from natural sources; (3) to study the biosynthesis and intracellular transport of proteins following their expression in various cell types; and (4) to elucidate structure-function relationships by analyzing the properties of normal and mutant proteins (see pages 16.3 and 16.4 in particular).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to put the sequences of copending Application No. 11/894,562 in plasmid vectors operably linked to promoters as taught by Sambrook et al and US Patent No. 4,889,806 because US Patent No. 4,889,806 specifically teaches that it is conventional to transfer genetic materials into plasmids or vectors and then transfer the plasmids or vectors into host cells and clonally propagate the genetic material and because Sambrook et al teach that cloned genes are conventionally expressed using expression vectors. One of ordinary skill in the art at the time the invention was made would have been motivated to put the sequences of copending Application No. 11/894,562 in plasmid vectors operably linked to promoters as Sambrook et al and US Patent No. 4,889,806 because Sambrook et al specifically teach that expressed cloned proteins are used to: (1) confirm the identity of a cloned gene by using immunological or functional assays to detect the encoded protein; (2) produce large amounts of proteins of biological interest that are normally available in only limited quantities from natural sources; (3) to study the biosynthesis and intracellular transport of proteins following their expression in various cell types; and (4) to elucidate structure-function relationships by analyzing the properties of normal and mutant proteins.

This is a provisional obviousness-type double patenting rejection.

12. All other objections and rejections recited in the Office Action of September 20, 2007 are withdrawn.

13. No claims allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER J. REDDIG whose telephone number is (571)272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

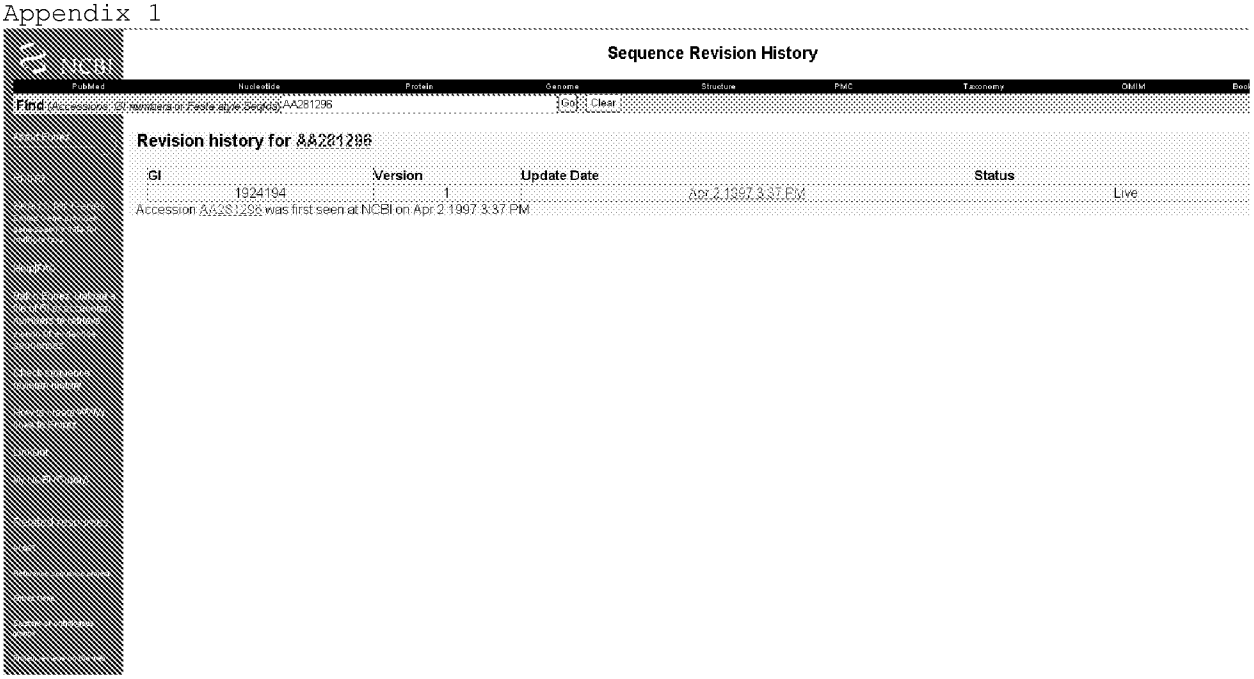
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Helms Larry can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/
Examiner, Art Unit 1642
/P. J. R./

/Karen A Canella/
Primary Examiner, Art Unit 1643

Appendix 1



Appendix 2